

The Effectiveness of FlowAid FA 100 Muscle Pump Activation System (MPA) at forefoot temperature changes in PAD patients.

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Background

One of the major symptoms of Peripheral Arterial Disease is a decrease in the temperature of the feet. Patients affected relate feelings of coldness, and of not being able to get, or keep their feet warm. It is also expressed through metabolic changes related to localized hypothermia. This condition is a direct result of the decreased local blood flow which prevents the warming effect of the blood from playing a role in the local temperature control. This coldness can also lead to feelings of pain, or a 'pins and needles' sensation.

In this study 10 patients with a primary diagnosis of Peripheral Arterial Disease were evaluated. The subjects were given a FlowAid FA 100 Muscle Pump Activation System to use for one, two hour session. IRB approval and informed consent was obtained. Patients were kept in a seated position with their legs elevated during this session. A digital Thermography Camera (FLIR Ex320) recorded temperatures in their feet during the two hour session as well as during a brief, up to one hour rest period afterward.

Results

Use of the FlowAid FA 100 device for two hours increased measured temperatures in all subjects. In the area of the plantar arch, where the changes generated by flow in the plantar arteries were measured, there was an average increase of 4.3 degrees Fahrenheit. In the heel the average change in temperature was 4.9 degrees centigrade, and in the forefoot the change was 5.1 degrees centigrade. The pattern of change was almost uniform across subjects, with the arch showing warming first, followed by the heel, and then the toes. The average time to reach maximum increase was 80 minutes. There was a gradual decrease in temperatures over the hour of rest after the device was removed.

Discussion

Skin temperature has long been utilized as an indicator for the level of circulation present in the lower extremities. On a cutaneous level, as the microcirculation just beneath the skin dilates, there is a hyperemic effect in the skin, and the measured temperature increases. Lately, this effect has been similarly related to a more macrovascular origination. One of the benchmark clinical symptoms in limb ischemia is decreased temperatures in the affected limb. That being said, when ischemia is treated and there is a fresh influx of blood, a concomitant increase in limb temperature would be expected. These increases in skin temperature should not be confused with temperature increases due to excess metabolic demand due to increased muscular

activity. The changes measured after use of the FlowAid FA 100 device is directly related to the newfound blood flow into the limb.

The FlowAid FA 100 device works by stimulating the muscles of the calf, causing an active physiologic pump for the vasculature of the lower extremity. By its four-electrode approach, the FlowAid FA 100 device maximizes the efficacy of the calf venous pump in patients who previously had weak activity in this group. By enhancing the venous outflow, the device causes a direct increase in the venous arterial pressure gradient, which results in an increased blood flow to the limb. In patients without total blockage of the vessels, this causes increased circulation along the vasculature to the levels of the microcirculation in the distal parts of the limb.

Utilizing digital thermography, skin temperature was measured on the plantar aspect of the foot. The main arterial anatomy in the area is the plantar arteries, made up of the medial and lateral plantar arterial arteries. The distal aspect of the foot is vascularized by an intricate complex of arterioles and capillaries. Increases in temperature over the plantar arch point to an increase in the influx of blood in the plantar arterial complex. This in and of itself is significant; however, thermography also measured an increase in skin temperature in the forefoot. This demonstrates a relative increase in the flooding of the microcirculatory system of the forefoot with fresh warm blood.

Conclusion

The FA 100 is a new muscle pump activation system of the calf muscle complex designed to treat PVD, and provide for new influx of blood flow to the lower extremities. In this study, utilizing digital thermography, the FA 100 demonstrated significant increases both in the arterial complex of the foot, as well as the microcirculatory complex of the forefoot.
